

Phillip A. Bennett (State Bar No. 241,809)
phillip.bennett@knobbe.com
 KNOBBE, MARTENS, OLSON & BEAR, LLP
 12790 El Camino Real
 San Diego, CA 92130
 Phone: (858) 707-4000
 Facsimile: (858) 707-4001

10 Attorneys for Plaintiff
KFx Medical Corporation

16	KFX MEDICAL CORPORATION, a Delaware corporation,)	Case no. 11cv1698 DMS (BLM)
17	Plaintiff and Counterdefendant,)	DECLARATION OF TATE SCOTT IN
18	v.)	SUPPORT OF PLAINTIFF'S MOTION
19	ARTHREX, INCORPORATED., a Delaware)	FOR SUMMARY JUDGMENT OF NO
20	corporation,)	INEQUITABLE CONDUCT IN
21	Defendant and Counterclaimant.)	CONNECTION WITH U.S. PATENT
22)	NO. 7,585,311
)	Date: September 10, 2012
)	Time: 9:00 a.m.
)	Courtroom 10, 2 nd Floor
)	Honorable Dana M. Sabraw

1 I, Tate Scott, declare and state as follows:

2 1. I am the President and CEO of KFx Medical Corporation ("KFx") in this
3 action. I submit this Declaration in Support of KFx's Motion for Summary Judgment of No
4 Inequitable Conduct in Connection with U.S. Patent No. 7,585,311. The following
5 statements are based on my personal knowledge unless otherwise indicated.

6 2. I joined KFx, which was then called 3i Medical, on April 5, 2005 as CEO.
7 During my career I have had over 30 years of experience in drugs, devices and combination
8 products. I have held positions with American Hospital Supply and Johnson & Johnson. I
9 have also been Chairman of Orquest, Inc. (Orthobiologics) through its sale in 2003 to DePuy,
10 a Johnson and Johnson Company, President of Situs Corporation, President at ATI
11 Corporation, President of Luther Medical Products (NASDAQ:LUTH), and currently on the
12 board of Scott Laboratories. I have attended countless surgeries and labs with surgeons over
13 the years, including numerous rotator cuff procedures and labs. I hold an AB and MBA
14 degrees from Duke University.

15 3. KFx was and is a privately held startup company headquartered in Carlsbad,
16 California. KFx was founded in 2003 with the goal of improving the quality and ease of a
17 variety of orthopedic surgical procedures performed on the shoulder, knee, foot, and ankle by
18 sports medicine surgeons. By the time I joined the company, KFx had invented bone anchors
19 and methods that enable tissue fixation with a minimum of suturing and manipulation with
20 particular application to the repair of torn rotator cuffs.

21 4. Rotator cuff repairs originally had been performed as "open" surgery,
22 requiring large incisions to be made in the shoulder. Advances in arthroscopic surgery
23 allowed surgeons to begin performing rotator cuff repairs arthroscopically. These
24 arthroscopic procedures involve making several tiny incisions in the shoulder and inserting
25 tube-like devices through the incisions to act as portals into the surgical site. A small camera
26 is inserted through one of the portals to allow the surgeon to view the surgical site on a
27 television monitor. Because arthroscopic repairs involve only tiny incisions in the shoulder,

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1 they are far less traumatic and invasive than open repairs, and lead to shorter, less expensive
2 hospital stays and faster recoveries.

3 5. Prior to the inventions of the '311 patent, arthroscopic techniques for repairing
4 torn rotator cuffs were difficult to execute and required exceptional skill and dexterity on the
5 part of the surgeon. For example, because the arthroscopic procedures were performed
6 through tiny incisions in the shoulder, it was difficult to manipulate the sutures within the
7 surgical site. Among other difficulties, this created difficulties in tying suture knots with
8 proper tension for ensuring that the repaired rotator cuff would remain in place and not re-
9 separate from the bone.

10 6. Shortly before joining the company in 2005 and for the next several months
11 after I joined I became familiar with KFx's technology, including knotless products and
12 techniques for treatment of rotator cuff tears. Certain of these products and techniques later
13 were referred to under the brand name SutureCross™. This approach involved the use
14 "knotless" bone anchors in a "double row" rotator cuff repair procedure. "Double row" refers
15 to the use of at least two points of attachment, typically a "medial" and "lateral" point of
16 attachment.

17 7. The knotless "double row" procedure generally involved the use of a first bone
18 anchor inserted underneath the rotator cuff tendon (also referred to as "medial" placement)
19 and a second anchor was inserted beyond the edge of the tendon ("lateral" placement). A
20 suture that was attached to the first bone anchor was passed through the tendon and over the
21 tendon toward the second bone anchor. The suture was tensioned and attached to the second
22 bone anchor without tying knots.

23 8. Upon joining the company I met with many potential investors to generate
24 interest in KFx and its technology. I also met with many members of the relevant surgical
25 community to demonstrate KFx's technology, learn about the MD's perspective on anatomic
26 reattachment of the rotator cuff and generate interest in KFx and its products. In 2005 this
27 included at least the following surgeons: Dr. JP Warner, Dr. James Esch, Dr. Peter Millett,

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1 Dr. Ken Yamaguchi, Dr. Joseph Tauro, Dr. Russ Warren, Dr. Chris Behr, Dr. Eric Carson and
2 others. Many of these surgeons had publications in the area of rotator cuff repair.

3 9. Shortly after I joined the company KFx filed a patent application on June 1,
4 2005. This application ultimately issued as the '311 patent in this case. I and others at KFx
5 worked with counsel in connection with the filing of this application. I was informed that
6 KFx had filed provisional applications prior to my joining the company and prior to this
7 patent application. At the time I did not have any occasion to review those provisional
8 applications and I do not recall ever substantively reviewing the contents of the provisional
9 applications.

10 10. Among the many materials I reviewed in 2005 when I joined the company was
11 an article by Dr. Peter Millett and others entitled "Mattress Double Anchor Footprint Repair:
12 A Novel, Arthroscopic Rotator Cuff Repair Technique", which I understand was published in
13 *Arthroscopy: The Journal of Arthroscopic and Related Surgery* in October 2004. A copy of
14 the article is attached as Exhibit A. This was one of a number of articles published at the time
15 that supported the concept of double row rotator cuff repairs to provide anatomic
16 reattachment of the rotator cuff. I thought the KFx approach was a substantial improvement
17 over the approach described in this article. The main drawback to the approach described in
18 the article was that it was a very complicated procedure involving suture passing and knot-
19 tying (all through a cannula while only able to watch the instruments on a TV-like screen)
20 that only the most expert surgeon could possibly perform. I understood that relatively few
21 surgeons at the time were proficient with all-arthroscopic rotator cuff repairs, and expected
22 even fewer would be comfortable with this very complicated approach to arthroscopic rotator
23 cuff repairs, involving in many cases twice as many anchors, and at least twice as many
24 knots.

25 11. As I mentioned above, Dr. Millett was one of the many surgeons I met with
26 after I joined KFx. I recall my first meeting with him was in the summer of 2005 in Vail,
27 Colorado.

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1 12. As I recall, I was introduced to Dr. Millett by a member of the KFx Board of
2 Directors, Dr. John Savarese. I reached out to Dr. Millett to show him what KFx was doing
3 and hopefully get him interested in our products and to help us move forward in the
4 marketplace. I was also interested in exploring the possibility of having him join our
5 Scientific Advisory Board. At that time, KFx's Scientific Advisory Board included a number
6 of surgeons. The Board was chaired by Dr. Joseph Tauro, a named inventor on the KFx '311
7 patent and one of the first surgeons to perform an arthroscopic rotator cuff repair and the first
8 to publish in a peer-reviewed journal on 2-3 year follow-up data on the arthroscopic repair of
9 a torn rotator cuff.

10 13. During the course of my very pleasant conversation with Dr. Millett we talked
11 about what he had done with arthroscopic rotator cuff repairs while at Harvard before he left
12 to join the Steadman Clinic in Vail, Colorado. As would be expected, his description was
13 entirely consistent with what I had recalled reading in his paper. After I described the KFx
14 method for performing a double row approach without having to tie the many knots, Dr.
15 Millett said he had not thought of doing his procedures in a knotless fashion. He added that
16 he wished he had. He also told me that he had discussed his idea for a double row surgical
17 method using a knot-tying approach with the Harvard Tech Transfer group and was told his
18 method was "not patentable."

19 14. The majority of our conversation was about the potential clinical advantages
20 of an anatomic like rotator cuff repair and how the KFx SutureCross approach could simplify
21 the procedure so that more surgeons could perform the procedure. Dr. Millett expressed an
22 interest in the KFx technology and we went on to set up several labs at his clinic where he
23 and other surgeons used our products and provided feedback to us. Dr. Millett also agreed to
24 join our Scientific Advisory Board since he believed his Consulting Agreement with Arthrex
25 did not preclude him from working products/procedures that Arthrex did not have. However,
26 after we announced in September 2006 that he would be joining our Scientific Advisory
27 Board, Dr. Millett called and told me that Arthrex had objected. Although Dr. Millett and I
28 discussed our common understanding that Arthrex had no knotless double-row rotator cuff

1 product in competition with KFx. I suggested and Dr. Miller agreed it would be best if we
2 simply terminated the Scientific Advisory Board arrangement rather than cause any
3 difficulties for Dr. Millett.

4 15. It never crossed my mind to even consider saying anything about my
5 conversation with Dr. Millett to the Patent Office. It was my practice and experience in
6 working in the medical device industry for the past thirty years that relevant background
7 literature and patents would all be submitted to the Patent Office, but I had never submitted a
8 description of a conversation. As far as I understood, the Millett article either had been or
9 would be submitted to Patent Office in connection with the KFx patent application. I always
10 understood the KFx knotless approach was a substantial advance over what Dr. Millett
11 described in his article, especially after Dr. Millet told me he wished he had thought of it.
12 Further, I did not believe Millett told me anything of substance about his work that was not
13 already in the article.

14 16. I understand that Arthrex has alleged that I intentionally deceived the Patent
15 Office by not relaying to them something that was mentioned in my conversation with Dr.
16 Millett. This is not true. The point I was interested in by approaching Dr. Millett was
17 discussing the potential clinical outcomes that might be achieved with a double row approach.
18 I did not believe Millett told me anything of substance about his work that was not already in
19 the article. The fact of when Dr. Millett did his work described in the article was of no
20 interest to me and I never even thought of mentioning it in relation to KFx's pending patent
21 application. I fail to see how anyone could read the article and not conclude he did the work
22 well before the article was published.

23 17. KFx was in discussions with Smith and Nephew regarding a possible license
24 to the '311 patent following its issuance on September 8, 2009. Smith and Nephew told us
25 they had "prior art" and during one telephone call Smith and Nephew representatives raised
26 three references to us. These were: (1) the above-referenced Millett article from October
27 2004; (2) an abstract that Smith and Nephew said was presented in Quebec, which I later
28 learned was presented at the 2004 Annual meeting of the American Orthopaedic Society for

1 Sports Medicine held June 24-27, 2004; and (3) an article titled “Arthroscopic Single-Row
2 vs. Double-Row Suture Anchor Rotator Cuff Repair”, which was published in *The American*
3 *Journal of Sports Medicine*, Vol. 33, No. 12 (2005). The two “new” references were related
4 to the October 2004 Article. And I later learned the abstract was specifically referenced in
5 the Article. See Ex. A at 879, Note 10.

6 18. Smith and Nephew never suggested to us that further information about when
7 Dr. Millett performed the work described in the publications was relevant. The call involved
8 patent lawyers for both Smith and Nephew and KFx.

9 19. We told Smith and Nephew that I was familiar with the 2004 article and that it
10 had already been submitted to the PTO. We also informed Smith and Nephew that we would
11 look at the others and consider submitting them in KFx’s pending applications. We promptly
12 did exactly that. For example, on December 8, 2009, we submitted the two other references
13 in our pending Application No. 549,105. A copy of the IDS is attached hereto as Exhibit B.
14 The references at issue are Nos. 172 and 173.

15 20. Our negotiations with Smith and Nephew continued. The above references
16 never came up again. Ultimately we did not agree to a license with Smith and Nephew.

17 21. I met with Dr. Millett again on or about January 27, 2011. At the time I knew
18 that the KFx patent was being infringed and I understood from my earlier conversations with
19 Dr. Millett that he could buttress the validity of the patent. I understood that if we could get
20 further more detailed documentation that Dr. Millett’s procedures were performed using a
21 knot-tying method that this might be useful to us. (Of course, I knew that any such
22 documentation would have to be redacted to comply with HIPAA.) During this conversation
23 Dr. Millett confirmed again that his procedures were all done with knot tying as he published,
24 but he was not interested in pulling together the archived documentation. He added that he
25 would not even know where to begin to search for the documentation. He suggested that
26 whatever documents might exist they likely would be in some boxes in a basement
27 somewhere at Harvard and “contained nothing more than what was in the article.” He also

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1 indicated that someone else had asked him for the documents and that he had refused them as
2 well.

3 22. By about early March 2011, I expected we would be submitting an
4 Information Disclosure Statement ("IDS") in connection with the pending reexamination
5 initiated at the request of an anonymous third party on January 11, 2011 that was granted by
6 the Patent Office on or about February 16, 2011. In connection with that, I expected that I
7 would be submitting a short statement to the Patent Office concerning my conversation with
8 Dr. Millett. I had never considered the issue before. I also expected that we would submit
9 the two additional Millett references brought to our attention by Smith and Nephew in 2009
10 after the '311 patent issued, which is exactly what we did back in December 2009. Before an
11 IDS was filed, however, we received the Notice of Intent to Issue the Reexamination
12 Certificate.

13 23. We submitted the IDS on April 12, 2011. This included my statement, a copy
14 of which is attached hereto as Exhibit C. The statement provided as follows:

15 An Information Disclosure Statement was filed on January 30, 2007 in the
16 application that issued as U.S. Patent No. 7,585,311. That Information Disclosure
17 Statement included as item #147 an article authored by Peter Millett et al., entitled
18 "Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair
technique," *Arthroscopy: The Journal of Arthroscopic and Related Surgery*,
20(8):875-879 (2004).

19 An Information Disclosure Statement is being filed herewith in the above-
20 identified re-examination that includes an abstract of which Peter Millett is a co-
21 author (Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor
22 Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004
23 Annual Meeting of the American Orthopaedic Society for Sports Medicine in
24 Quebec, Canada, publication date unknown) and another article of which Peter
Millett is a co-author (Mazzocca et al., "Arthroscopic Single-Row Versus Double-
Row Suture Anchor Rotator Cuff Repair," *The American Journal of Sports
Medicine*, 33:1861 (2005)).

25 I had a conversation with Peter Millett during which he told me that the
26 procedures referenced in the 2004 article had been performed in the two years
preceding publication of the article.

27 He also confirmed that all of the procedures were performed by tying
28 knots as described in the 2004 article.

1 24. I understand the Patent Office refused to consider the IDS because it came
2 after the Notice of Intent to Issue the Reexamination Certificate. We thereafter filed a
3 petition to have the Patent Office consider it because the IDS was filed within the two-month
4 deadline specified in the Patent Office regulations, i.e. within two months of the February 16,
5 2012 Order Granting the Request for Ex Parte Reexamination. At the time I was not familiar
6 with these rules relating to the timing of an IDS or this apparent conflict in the rules. A copy
7 of the petition is attached hereto as Ex. D. The Patent Office denied that petition. That
8 decision is attached hereto as Exhibit E.

9 25. I understand that Arthrex has alleged that I intentionally delayed the filing of
10 my statement included in the reexamination IDS in order to deceive the Patent Office into
11 allowing the '311 patent reexamination to issue. This is not true. I have never done anything
12 or failed to do anything to deceive or attempt to deceive the Patent Office.

13 I declare under penalty of perjury under the laws of the United States of America that
14 the foregoing is true and correct.

15 Executed on July 11, 2012 in Carlsbad, California.

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18 _____
Tate Scott

PROOF OF SERVICE

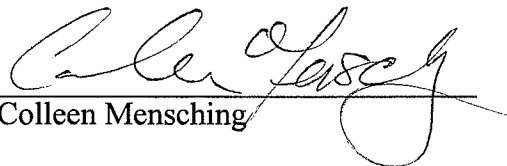
I hereby certify that on July 13, 2012, I caused the **DECLARATION OF TATE SCOTT IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT IN CONNECTION WITH U.S. PATENT NO. 7,585,311** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

Michael A. Tomasulo
tomasulom@dicksteinshapiro.com
DICKSTEIN SHAPIRO LLP
2049 Century Park East, Suite 700
Los Angeles, CA 90067
T: 310-772-8300

Charles W. Saber
saberc@dicksteinshapiro.com
Salvatore P. Tamburo
tamburos@dicksteinshapiro.com
Megan S. Woodworth
woodworthm@dicksteinshapiro.com
S. Gregory Herrman
herrmanG@dicksteinshapiro.com
DICKSTEIN SHAPIRO LLP
1825 Eye Street Northwest
Washington, DC 20006
T: 202-420-2200

I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the forgoing is true and correct.

Executed on July 13, 2012, at San Diego, California.


Colleen Mensching

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EXHIBIT A

Technical Note

Mattress Double Anchor Footprint Repair: A Novel, Arthroscopic Rotator Cuff Repair Technique

Peter J. Millett, M.D., M.Sc., Augustus Mazzocca, M.D., and Carlos A. Guanche, M.D.

Abstract: In an effort to increase the immediate strength of a rotator cuff repair and to simulate the standard open reconstruction with its effective suture fixation, we have developed a novel technique for suture anchor reconstruction of the rotator cuff. The technique, termed mattress double anchor (MDA), is simple and adaptable. It makes use of 2 suture anchors that are placed independently and then connected by a suture loop. The technique produces a repair construct that distributes the stress across 2 anchors. The method also restores a large surface area for healing between the rotator cuff and the tuberosity. **Key Words:** Suture anchor—Rotator cuff repair—Rotator cuff footprint—Double row.

The surgical approach to the rotator cuff has evolved over the last several years and there is great interest in arthroscopic repair of rotator cuff tears. There are many techniques that have been developed to improve the initial strength of the repair. By increasing the initial repair strength, earlier and more aggressive rehabilitation can be allowed. Immobilization is decreased, which hastens recovery and return of function. Concerns about failure of fixation at the cuff-bone and the cuff-suture interface often lead surgeons to limit early motion.

The weak links in rotator cuff repair are at the cuff-suture interface and at the suture-bone interface. Several techniques have been developed to address these issues. Historically, the most notable are (1) the transosseous

suture configuration, which compresses the cuff onto the tuberosity, and (2) the modified Mason-Allen suture grasping technique, which maximizes resistance to suture-tendon pullout.¹ In addition to strength, the technique of the repair has also been shown to affect the surface area of the repair, which undoubtedly affects the potential for healing between the cuff tendon and the underlying bone.² The footprint of the rotator cuff on the tuberosity is quite broad³ at approximately 15 mm, and double row fixation has been advocated as a means to restore this surface area for healing.^{4,5}

Most modern arthroscopic repair techniques have used suture anchors because of the technical difficulties with transosseous techniques.⁶⁻⁸ Furthermore, most of the arthroscopic techniques rely on simple sutures through the rotator cuff tendon, which are undoubtedly a weak link.

In an effort to address many of these issues, we have developed a novel repair strategy that closely approximates both the transosseous suture configuration and the modified Mason-Allen tissue-grasping technique in an arthroscopic fashion. The technique simplifies suture management and eliminates the need to pass sutures multiple times. The purpose of this article is to describe the technique that we have termed the mattress double anchor technique (MDA).

From the Harvard Shoulder Service, Harvard Medical School, Brigham & Women's Hospital, Boston, Massachusetts (P.J.M.); the Shoulder Service, University of Connecticut, Farmington, Connecticut (A.M.); and the Southern California Orthopaedic Institute, Van Nuys, California (C.A.G.), U.S.A.

Address correspondence and reprint requests to Peter J. Millett, M.D., M.Sc., Harvard Shoulder Service/Sports Medicine, Brigham & Women's Hospital, 75 Francis St, Boston, MA 02115, U.S.A. E-mail: pmillett@partners.org

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doi:10.1016/j.arthro.2004.07.015

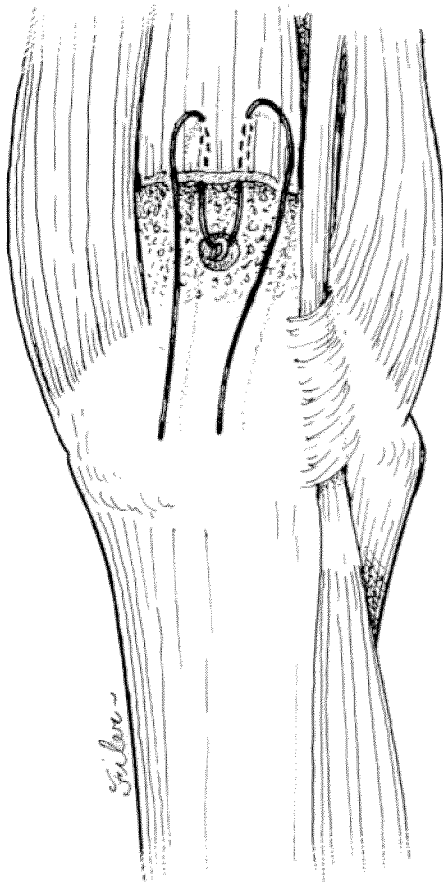


FIGURE 1. The medial anchor is placed in the medial border of the footprint at the articular margin and the sutures are passed in a mattress configuration so that there are anterior and posterior limbs. The sutures should be passed through the tendon 10 to 15 mm medial to the edge so that the desired amount of tendon will be repaired over the footprint.

TECHNIQUE

The standard approaches are used with respect to patient selection and decision-making regarding the possibility of an arthroscopic repair.⁶⁻⁸ Once the decision is made to perform this type of repair, the surgeon should perform a thorough debridement of the rotator cuff, prepare the tuberosity by removing soft tissues, and plan the repair.

Following debridement of the edges of the cuff from an intra-articular and extra-articular position, a thorough bursectomy is performed. An acromioplasty is performed as needed. The rotator cuff footprint is re-established by debriding the greater tuberosity down to bleeding corticocancellous bone.

No attempt is made to decorticate the area or to create a trough so as to avoid weakening the fixation points for the anchors.

The first anchor, termed the medial anchor, is placed at the articular margin. Tingart et al.⁹ have recently shown

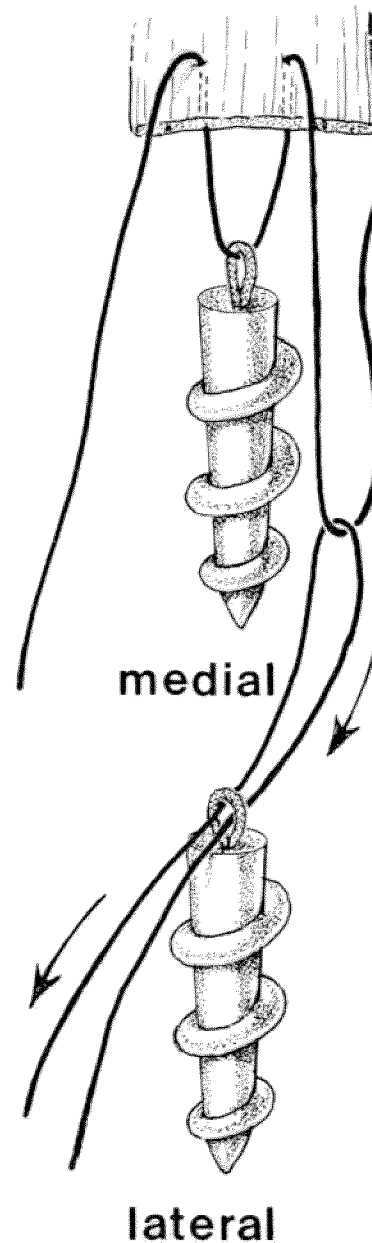


FIGURE 2. Illustration showing how the suture anchors are linked with a single suture. The lateral anchor must be preloaded with a loop of suture before insertion.

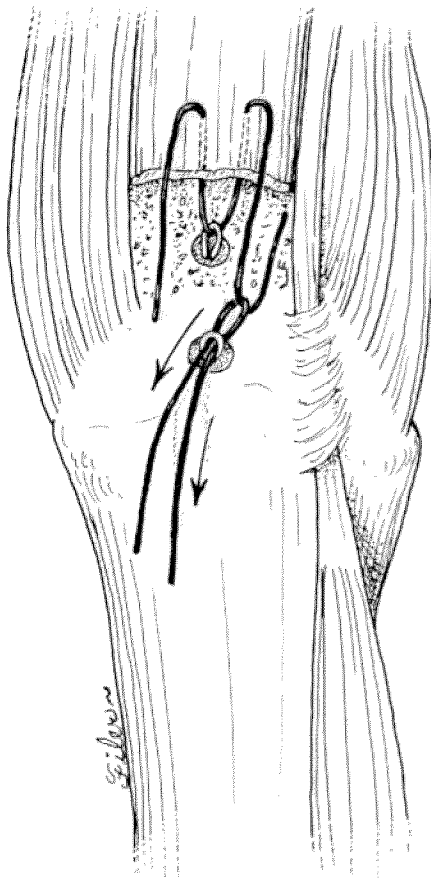


FIGURE 3. The lateral anchor is placed laterally on the tuberosity. One limb from the medial suture is pulled through the loop and then shuttled through the eyelet of the lateral anchor.

that this bone has the best quality with the highest bone mineral density.⁹ The medial anchor is a 5.0-mm Biocorkscrew anchor (Arthrex, Naples, FL), although in cases where bone quality is an issue, a 6.5-mm Biocorkscrew anchor may be used. It is imperative to use an anchor with a suture eyelet because the technique requires that the sutures slide easily through the eyelets and requires the passage of a suture through the eyelet of the lateral anchor after the anchor has been inserted (in situ). An anchor with this type of eyelet design is essential. A metal eyelet will not permit passage of the sutures in situ and, furthermore, will not allow the sutures to slide easily, resulting in abrasion and possible breakage. The medial anchor should be loaded with 2 sutures (No. 2 Fiberwire, Arthrex) in order to repair the rotator cuff tendon with the use of a tissue-grasping technique.

As the medial anchor is placed, care is taken to align the eyelet of the anchor perpendicular to the

articular margin. This area has the best bone quality of the tuberosity and ensures that the medial insertion of the rotator cuff will be re-established. This orientation of the anchor allows the sutures to be passed so that there will be anterior and posterior suture limbs that will slide easily (Fig 1). Suture passage through the rotator cuff is accomplished using any one of a variety of standard techniques.

The second anchor, termed the lateral anchor, is placed about 1 cm lateral to the first anchor. This anchor can be either a 5.0- or 6.5-mm Biocorkscrew, depending on the bone quality. This anchor should be inserted with a loop of suture across the eyelet, rather than 2 single limbs. The sutures should be preloaded in this configuration before insertion (Fig 2). One of the loops will be used to pass a suture from the medial anchor through the eyelet of the lateral in situ anchor (Fig 3). It is essential to assure that the suture is passed

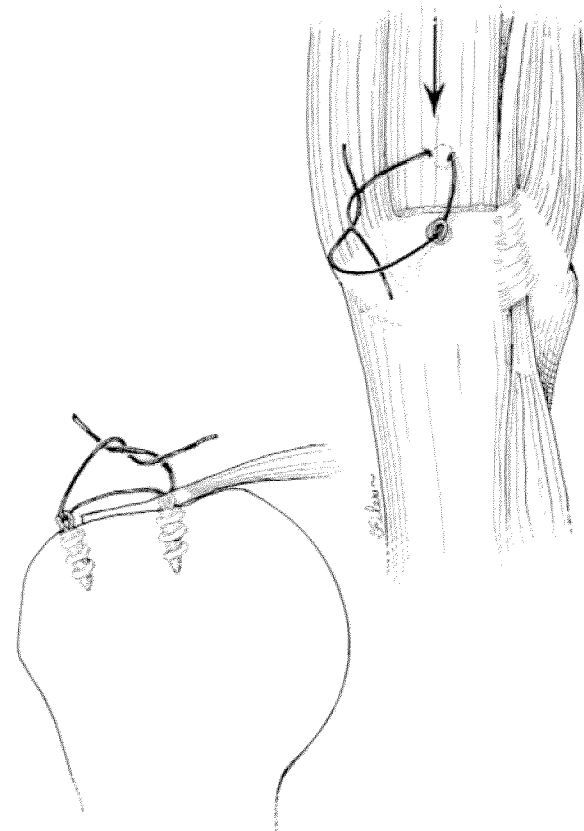


FIGURE 4. The suture linked between 2 anchors is then secured using standard arthroscopic knot tying techniques. The tendon is compressed onto the tuberosity and a broad footprint is recreated. In the coronal view, the configuration is similar to that achieved with transosseous techniques.

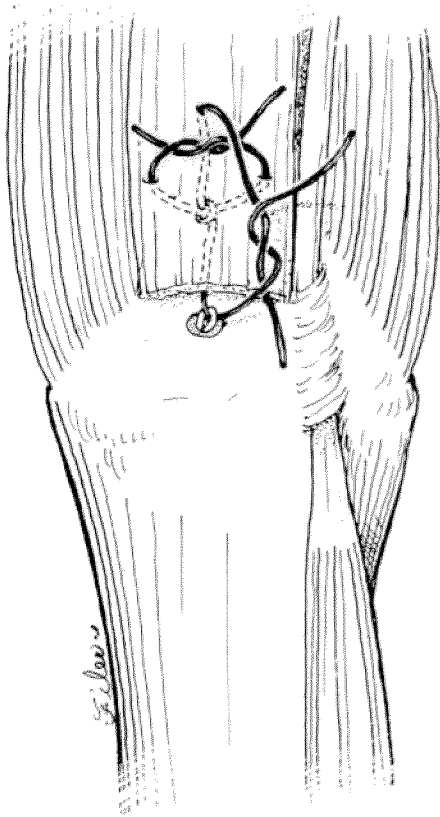


FIGURE 5. An alternative suture configuration with interlocking of the sutures to prevent cutout from the tendon.

in a medial-to-lateral direction through the lateral anchor, to avoid twisting the suture in the lateral anchor eyelet, because this would inhibit sliding and potentially compromise the repair. Knot tying is then accomplished with standard sliding locking knot techniques. This creates a mattress suture pattern between the 2 anchors that compresses the underlying rotator cuff, hence the term mattress double anchor (Fig 4).

One set of 2 anchors is used per centimeter.⁷ The spacing of multiple anchors should be carefully planned to avoid overcrowding of the anchors in the tuberosity.

Alternative suture configurations can be used where a second suture is tied in a mattress configuration medially, where the sutures are oriented in a suture-grasping configuration similar to that described by P. St. Pierre (personal communication, October 2003) for a single-anchor technique (Fig 5), or where the sutures criss-cross between 2 sets of anchors creating maximum compression over a large surface area (Fig 6).

BIOMECHANICAL AND CLINICAL RESULTS

Biomechanical testing has been performed and shows this technique to be as strong as traditional single-row techniques with better restoration of surface area and less chance for bone failure.¹⁰ It has strength similar to other double-row anchor patterns with fewer passes of suture through the rotator cuff. The authors have used the technique clinically in more than 50 cases without any adverse effects.

DISCUSSION

The MDA technique simulates a traditional transosseous repair with a tendon-grasping suture configura-

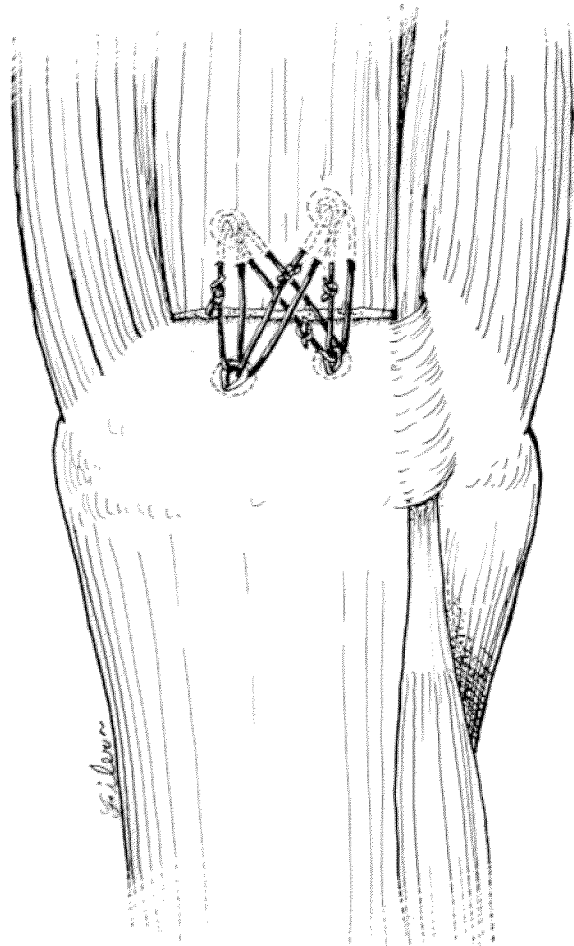


FIGURE 6. The complex criss-cross configuration where sutures from 4 separate anchors can be interlocked to maximize tendon compression and repair site surface area.

tion, yet it can be performed arthroscopically. The technique allows the reapproximation of the rotator cuff tendon solidly onto the greater tuberosity while increasing the area available for healing. Furthermore, the cross-linking of the anchors compresses the rotator cuff, decreases the risk of bone failure, minimizes the number of passes of sutures through the tendon, and eliminates prominent edges to the cuff. It seems likely that the construct decreases the chances of bone failure because of the increased number of fixation points.

The strength of the MDA and its restoration of the rotator cuff footprint are excellent. The MDA repair is as strong as traditional suture anchor techniques with better restoration of the footprint. The MDA technique is reproducible and easily performed by surgeons proficient in arthroscopic rotator cuff repairs. While the MDA technique is adaptable and can be carried out in different suture configurations and in open procedures, there are certain tears, such as chronic retracted tears, that may be better treated with single-row fixation or margin convergence to avoid excess tension on the repair.

In summary, the MDA technique is a novel arthroscopic rotator cuff repair strategy that restores the anatomy and allows the creation of a tendon-grasping and a bone-grasping construct. The surface area for healing is maximized and early stability is achieved. The technique depends on an anchor that has suture eyelets that allow suture passage in situ and also allows excellent suture sliding. The MDA technique minimizes the number of suture passes through the rotator cuff tissue. We find the technique to be repro-

ducible and simple to use, while optimizing the initial strength and geometry of the rotator cuff repair construct.

REFERENCES

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2. Apreleva M, Ozbaydar M, Fitzgibbons PG, Warner JJ. Rotator cuff tears: The effect of the reconstruction method on three-dimensional repair site area. *Arthroscopy* 2002;18:519-526.
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8. Tauro JC. Arthroscopic rotator cuff repair: Analysis of technique and results at 2 and 3-year follow-up. *Arthroscopy* 1998;14:45-51.
9. Tingart MJ, Apreleva M, Zurakowski D, Warner JJ. Pullout strength of suture anchors used in rotator cuff repair. *J Bone Joint Surg Am* 2003;85:2190-2198.
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EXHIBIT B

Docket No.: KFX.003DV1

Customer No. 20995

INFORMATION DISCLOSURE STATEMENT

Applicant	: Green et al.
App. No	: 12/549,105
Filed	: August 27, 2009
For	: SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	: Unknown
Art Unit	: 3773
Conf No.	: 8338

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 178 references; 169 of these references are of record in U.S. patent application No. 11/143,007 filed June 1, 2005, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Accordingly, copies of the references are not submitted pursuant to 37 C.F.R. § 1.98(d), with the exception of Reference numbers 172 and 173 which are new and are submitted herewith.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12-8-09

By: Ryan E. Melnick

Ryan E. Melnick
Registration No. 58,621
Attorney of Record
Customer No. 20995
(619) 235-8550

8144174/stk 111909

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/549105
	Filing Date	August 27, 2009
	First Named Inventor	Green et al.
	Art Unit	3773
	Examiner	Unknown
SHEET 1 OF 7	Attorney Docket No.	KFX.003DV1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	Re. 36,289	08-31-1999	Le et al.	
	2	3,623,192	05-05-1969	Button	
	3	4,210,148	07-01-1980	Stivala	
	4	4,532,926	08-06-1985	O'Holla	
	5	4,796,612	01-10-1989	Reese	
	6	4,898,156	02-06-1990	Gattuma et al.	
	7	5,013,316	05-07-1991	Goble et al.	
	8	5,192,303	03-09-1993	Gattuma et al.	
	9	5,219,359	06-15-1993	McQuilkin et al.	
	10	5,224,946	07-06-1993	Hayhurst et al.	
	11	5,269,784	12-14-1993	Mast	
	12	5,336,240	08-09-1994	Tornier et al.	
	13	5,372,604	12-13-1994	Trott	
	14	5,417,712	05-23-1995	Whittaker et al.	
	15	5,423,858	06-13-1995	Bolanos et al.	
	16	5,423,860	06-13-1995	Lizardi et al.	
	17	5,472,452	12-05-1995	Trott	
	18	5,478,353	12-26-1995	Yoon	
	19	5,500,001	03-19-1996	Trott	
	20	5,527,341	06-18-1996	Gogolewski et al.	
	21	5,527,343	06-18-1996	Bonutti	
	22	5,543,012	08-06-1996	Watson et al.	
	23	5,545,180	08-13-1996	Le et al.	
	24	5,569,306	10-29-1996	Thal, R.	
	25	5,575,801	11-19-1996	Habermeyer et al.	
	26	5,578,057	11-26-1996	Wenstrom, Jr.	
	27	5,584,835	12-17-1996	Greenfield, J.	
	28	5,591,207	01-07-1997	Coleman	
	29	5,634,926	06-03-1997	Jobe	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T¹ - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/549105
	Filing Date	August 27, 2009
	First Named Inventor	Green et al.
	Art Unit	3773
SHEET 2 OF 7		Examiner
		Unknown
		Attorney Docket No.
		KFX.003DV1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	5,683,419	11-04-1997	Thal	
	31	5,690,676	11-25-1997	DiPoto et al.	
	32	5,697,950	12-16-1997	Fucci et al.	
	33	5,720,765	02-24-1998	Thal	
	34	5,725,557	03-10-1998	Gattorna et al.	
	35	5,769,894	06-23-1998	Ferragamo	
	36	5,800,436	09-01-1998	Lerch	
	37	5,814,072	09-29-1998	Bonutti	
	38	5,891,168	04-06-1999	Thal	
	39	5,948,001	09-07-1999	Larsen	
	40	5,948,002	09-07-1999	Bonutti	
	41	5,951,590	09-14-1999	Goldfarb	
	42	5,964,769	10-12-1999	Wagner et al.	
	43	6,010,525	01-04-2000	Bonutti et al.	
	44	6,013,077	01-11-2000	Harwin	
	45	6,013,083	01-11-2000	Bennett	
	46	6,027,523	02-22-2000	Schmieding	
	47	6,045,573	04-04-2000	Wenstrom, Jr. et al.	
	48	6,056,751	05-02-2000	Fenton, Jr.	
	49	6,063,106	05-16-2000	Gibson	
	50	6,093,201	07-25-2000	Cooper et al.	
	51	6,093,301	07-25-2000	Van Atta	
	52	6,099,547	08-08-2000	Gellman et al.	
	53	6,110,207	08-29-2000	Eichhorn et al.	
	54	6,117,160	09-12-2000	Bonutti	
	55	6,117,161	09-12-2000	Li et al.	
	56	6,126,677	10-03-2000	Ganaja et al.	
	57	6,149,669	11-21-2000	Li	
	58	6,200,330	03-13-2001	Benderev et al.	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T¹ - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/549105
	Filing Date	August 27, 2009
	First Named Inventor	Green et al.
	Art Unit	3773
	Examiner	Unknown
SHEET 3 OF 7	Attorney Docket No.	KFX.003DV1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,241,749 B1	06-05-2001	Rayhanabad	
	60	6,245,082 B1	06-12-2001	Gellman et al.	
	61	6,280,474 B1	08-28-2001	Cassidy et al.	
	62	6,293,961 B2	09-25-2001	Schwartz et al.	
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	67	6,391,030 B1	05-21-2002	Wagner et al.	
	68	6,423,065 B2	07-23-2002	Ferree	
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	74	6,520,980 B1	02-18-2003	Foerster	
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	86	6,660,023	12-09-2003	McDevitt et al.	
	87	6,605,096 B1	08-12-2003	Ritchart	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T¹ - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/549105
	Filing Date	August 27, 2009
	First Named Inventor	Green et al.
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 4 OF 7	Attorney Docket No.	KFX.003DV1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	6,635,073 B2	10-21-2003	Bonutti	
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	90	6,652,561 B1	11-25-2003	Tran	
	91	6,660,008 B1	12-09-2003	Foerster et al.	
	92	6,673,094	01-06-2004	McDevitt et al.	
	93	6,712,830	03-30-2004	Vernon S. Esplin	
	94	6,770,076 B2	08-03-2004	Foerster	
	95	6,780,198 B1	08-24-2004	Gregoire et al.	
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	97	6,984,241 B2	01-10-2006	Lubbers et al.	
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	99	7,041,120	05-09-2006	Li et al.	
	100	7,056,333 B2	06-06-2006	Walshe	
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	113	2002/0019649 A1	02-14-2002	Sikora et al.	
	114	2002/0029066 A1	03-07-2002	Foerster	
	115	2002/0077631 A1	06-20-2002	Lubbers et al.	
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Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/549105
	Filing Date	August 27, 2009
	First Named Inventor	Green et al.
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 5 OF 7	Attorney Docket No.	KFX.003DV1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	117	2002/0128684 A1	09-12-2002	Foerster	
	118	2002/0169478 A1	11-14-2002	Schwartz et al.	
	119	2002/0188305 A1	12-12-2003	Foerster et al.	
	120	2003/0018358 A1	01-23-2003	Saadat	
	121	2003/0088270 A1	05-08-2003	Lubbers et al.	
	122	2003/0105591	06-05-2003	Hagiwara	
	123	2003/0149448 A1	08-07-2003	Foerster et al.	
	124	2003/0167072 A1	09-04-2003	Oberlander	
	125	2003/0181925 A1	09-25-2003	Bain et al.	
	126	2003/0191498 A1	10-09-2003	Foerster et al.	
	127	2003/0195528 A1	10-16-2003	Ritchart	
	128	2003/0195563 A1	10-16-2003	Foerster	
	129	2003/0195564 A1	10-16-2003	Tran et al.	
	130	2003/0204204 A1	10-30-2003	Bonutti	
	131	2003/0236555 A1	12-25-2003	Thornes	
	132	2004/0002735 A1	01-01-2004	Lizardi et al.	
	133	2004/0024420 A1	02-05-2004	Lubbers et al.	
	134	2004/0044366 A1	03-04-2004	Bonutti et al.	
	135	2004/0102779 A1	05-27-2004	Nesper et al.	
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	137	2004/0133238 A1	07-08-2004	Cerier	
	138	2004/0193217 A1	09-30-2004	Lubbers et al.	
	139	2004/0225325 A1	11-11-2004	Bonutti	
	140	2004/0243178 A1	12-02-2004	Haut et al.	
	141	2004/0254609 A1	12-16-2004	Esplin	
	142	2004/0267317 A1	12-30-2004	Higgins et al.	
	143	2005/0027307 A1	02-03-2005	Schwartz et al.	
	144	2005/005502 A1	03-10-2005	Lombardo et al.	
	145	2005/0240199 A1	10-27-2005	Martinek et al.	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T¹ - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/549105
	Filing Date	August 27, 2009
	First Named Inventor	Green et al.
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 6 OF 7	Attorney Docket No.	KFX.003DV1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	146	2005/0240226 A1	10-27-2005	Foerster et al.	
	147	2005/0245932 A1	11-03-2005	Fanton et al.	
	148	2005/0288682 A1	12-29-2005	Howe	
	149	2005/283158 A1	12-22-2005	West	Para 0042, 0043, 0047, 0048
	150	2006/0106423 A1	05-18-2006	Weisel et al.	
	151	2006/0116719 A1	06-01-2006	Martinek	
	152	2006/0178702 A1	08-10-2006	Pierce et al.	
	153	2006/0235413 A1	10-19-2006	Denham et al.	
	154	2006/0271060 A1	11-30-2006	Gordon	
	155	2006/0271105 A1	11-30-2006	Foerster et al.	
	156	2006/0293710 A1	12-28-2006	Foerster et al.	
	157	2007/0142861	06-21-2007	Burkhart	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	158	SU 1600713	10-23-1990	Don Med Inst.		
	159	WO 2001/54586 A1	08-02-2001	Shoulderon Ltd.	Pg 9, lines 1-11; Pg 9 lines 23-27; Pg 10, lines 4-14; Figs 3-5	
	160	WO 2001/67962 A2	09-20-2001	Rösch		
	161	WO 2002/11630 A	02-14-2002	Cleveland Clinic Foundation		
	162	WO 2002/21998 A2	03-21-2002	Axya Medical Inc.	Para 0033, 0037, 0043	
	163	WO 2003/065904 A1	08-14-2003	Opus Medical, Inc.		
	164	WO 2004/062506 A1	07-29-2004	Linovatec Biomaterials OY		
	165	WO 2005/112786 A2	12-01-2005	Ethicon Endo-Surgery, Inc.		
	166	WO 2005/112788 A2	12-01-2005	Arthrocare Corporation		
	167	WO 2006/060035 A2	06-08-2006	3I Medical Corp.		
	168	WO 2006/067548 A1	06-29-2006	Arthrex, Inc.		
	169	WO 2006/128092 A2	11-30-2006	Arthrocare Corporation		

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/549105	
	Filing Date	August 27, 2009	
	First Named Inventor	Green et al.	
	Art Unit	3773	
(Multiple sheets used when necessary)		Examiner	Unknown
SHEET 7 OF 7		Attorney Docket No.	KFX.003DV1

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	170	WO 2007/084714 A2	07-26-2007	Kim	Para 0031-0033; Para 0045; Figs 2, 6	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	171	Lo et al., Double-row arthroscopic rotator cuff repair: re-establishing the footprint of the rotator cuff, <i>Arthroscopy: The Journal of Arthroscopic and Related Surgery</i> , 19(9):1035-1042 (2003).	
	172	Mazzocca et al., "Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair," <i>The American Journal of Sports Medicine</i> , 33:1861 (2005).	
	173	Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown.	
	174	Millett et al., Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique, <i>Arthroscopy: The Journal of Arthroscopic and Related Surgery</i> , 20(8):875-879 (2004).	
	175	Waltrip, Robert L., "A Biomechanical Comparison of Three Techniques," <i>The American Journal of Sports Medicine</i> , Vol. 31, No. 4, pp. 493-497.	
	176	International Search Report and Written Opinion of the International Searching Authority dated September 6, 2006 from PCT/US2005/019454.	
	177	International Preliminary Report on Patentability dated January 25, 2007 from PCT/US2005/019454.	
	178	PCT, Invitation to Pay Additional Fees, mailed May 13, 2008, for International Application No. PCT/US2007/083662.	

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111909

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T¹ - Place a check mark in this area when an English language Translation is attached.

EXHIBIT C

Docket No.: KFX.003RX

Customer No. 20995

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Michael L. Green, et al.
Re-exam. No.	:	90/011430
Filed	:	January 11, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Clark, Jeanne Marie
Art Unit	:	3993
Conf No.	:	1162

STATEMENT OF TATE SCOTT

Commissioner of Patent
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Tate Scott, declare and state that:

1. I am CEO of KFx Medical Corp., the assignee of U.S. Patent No. 7,585,311 upon which the above-identified re-examination is based.

2. An Information Disclosure Statement was filed on January 30, 2007 in the application that issued as U.S. Patent No. 7,585,311. That Information Disclosure Statement included as item #147 an article authored by Peter Millett et al., entitled "Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique," *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, 20(8):875-879 (2004).

3. An Information Disclosure Statement is being filed herewith in the above-identified re-examination that includes an abstract of which Peter Millett is a co-author (Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown) and another article of which Peter Millett is a co-author (Mazzocca et al., "Arthroscopic Single-Row Versus Double-

Application No.: 90/011430
Filing Date: January 11, 2011

Row Suture Anchor Rotator Cuff Repair," *The American Journal of Sports Medicine*, 33:1861 (2005)).

4. I had a conversation with Peter Millett during which he told me that the procedures referenced in the 2004 article had been performed in the two years preceding publication of the article.

5. He also confirmed that all of the procedures were performed by tying knots as described in the 2004 article.

6. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Date:

Apr. 12, 2011

Tate Scott
Tate Scott